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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/735,273	12/11/2000	Edwin A. Clark	WIBL-P01-534	3583

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EXAMINER

SWITZER, JULIET CAROLINE

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 05/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/735,273

Applicant(s)

CLARK ET AL.

Examiner

Juliet C. Switzer

Art Unit

1634

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 07 May 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 07 May 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 12, 14, 17, 19, 29 and 36-41.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____.

Continuation of 2. NOTE: The proposed amendment cannot be entered because the amendment is not in proper form as the listing of claims does not include the disposition of all claims throughout prosecution.

Continuation of 5. does NOT place the application in condition for allowance because: With regard to the new matter rejection, applicant points out that RhoC is positively recited throughout the application. This is not disputed. However, there is no basis identified in the specification for the exclusion of RhoC. There is no teaching in the specification of a genus of gene products which alter the actin-based cytoskeleton that excludes RhoC. Applicant refers to the *In re Johnson* in their arguments, however the instant case differs from the facts in *Johnson*, because in the instant case, unlike *Johnson*, there is not broad disclosure of a large number of working examples defining the genus and artificial sub-genus, but instead only a showing of three possible species within the extrapolated genus, and with regard to one of those species (FN) there is question as to the enablement of even that species, as discussed in the rejections of record. Furthermore, in *Johnson*, the specification described a genus of polymers with common structure differing only in substituents, however in the instant case the gene products being recited in the specification do not share a common core or structure or function, instead the genus encompasses a wide variety of types of gene products which are only loosely related. The rejection is maintained.


Applicant traverses the enablement rejection. Applicant disregards the references that demonstrate the unpredictability with regard to fibronectin expression stating that the expression detection methods using arrays used in the specification have higher sensitivity and specificity. Nonetheless, this does not overcome the fact that there is a high degree of unpredictability for the practice of the method, which does not require the use of any particular methodology, and encompasses the use of a broad range of gene products as markers. The claims in fact only require the study of "gene products" of which the proteins studied in the cited references certainly qualify.

While it is agreed that the actual taking of biological samples is routine in the prior art, the claims imply that any biological sample can be used to assay for any metastatic condition, an implication which is not supported by the claims.

To support the validity of the cell line models and tumors used in the instant specification, applicant cites a number of exhibits (references). However, these are not considered as they are not timely filed, as they are filed after final when prosecution was closed.

Nonetheless, even if the models are valid, the claims are not commensurate in scope with the examples, as expression of only three genes was shown, FN, RhoC, and ThymosinB4. Furthermore, the unpredictability in the prior art has been established, as well as the breadth of the claims, and the lack of working examples commensurate in scope with the broad claims. The enablement rejection is maintained.

Applicant points out that Van Gronigen does not teach determining gene expression of laminin B2 mRNA in melanoma metastasis lesions. This argument is not commensurate in scope with the claims which do not recite melanoma metastasis lesions. Applicant's comments about MIA are considered but not persuasive. Van Gronigen et al. themselves suggest MIA is a potential marker for stages of melanoma progression (discussion, p. 6241). Applicant's arguments are not sufficient to overcome the disclosure of Van Gronigen, as attorney's arguments cannot replace evidence on the record. Applicant argues that there is no teaching that NM23 is involved with the actin-based cytoskeleton, but this is an necessary property of a laminin gene product, regardless of whether it is pointed out in the references. The rejection is maintained.


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600